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**International Academy
of Compounding Pharmacists**

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11:20 AM JUL 27 2000

July 21, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Request for Comments on FDA Concept Paper: Drug Products That Present
Demonstrable Difficulties for Compounding Because of Reasons of Safety or
Effectiveness**

Dear Sir/Madam:

The International Academy of Compounding Pharmacists ("IACP") respectfully requests that the deadline for comments regarding "FDA Concept Paper: Drug Products that Present Demonstrable Difficulties for Compounding Because of Reasons of Safety or Effectiveness" ("Concept Paper") be extended 90 days once all materials have been placed on the docket.

This 47-page document was posted on FDA's website on June 29, 2000. The FDA has requested comments within 45 days, by August 15, 2000. The length of this document warrants a 90-day comment period. In order for IACP to review and evaluate the impact this document will have on its membership – 1500 pharmacists representing tens of thousands of physicians and millions of patients – the comment time of 90 days is needed.

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In addition, the comment process has been complicated by the absence of the extensive bibliography accompanying the Concept Paper. As of today, this bibliography has not been entered into the docket. Essentially the FDA has requested comments on materials without making these materials available. As a result, the comment period should not begin until all materials are available in the docket.

Therefore for these reasons and for IACP's interest in submitting thoughtful comments, I request that a 90-day comment period be allowed starting when all materials are available.

Sincerely,



Shelly Capps

Executive Director